

# 13

## Medical Product Safety

### Goal

Ensure the safest and most effective use of medical products.

### Overview

Over the last two to three decades, several federal programs and initiatives have been developed to assure the safe and effective use of medical products. Many states including Kentucky have implemented programs designed to complement or enhance these federal initiatives. For example, in 1998, Kentucky implemented a Controlled Substances Act and promulgated corresponding regulations. In the last 5-6 years Kentucky has also developed a uniform electronic database which captures information on prescriptions for controlled substances. This database has proven to be a significant enhancement in assuring the safe use of controlled substances.

Misuse and abuse of controlled drugs is a serious problem in Kentucky. Over the last two years, articles have appeared in the *Lexington Herald Leader* concerning abuse of controlled substances by both Medicaid and non-Medicaid individuals particularly in the mountains of Eastern and Southeastern Kentucky. Abuse of controlled substances is harmful to individuals and families as well as to communities and the state at large. The individual, family, and society all bear the consequences of addiction. An electronic data system which captures prescriptions for controlled substances is essential in determining the extent of the problem and in creating solutions to curb continued abuse.

### Summary of Progress

On July 1, 1999, the KASPER (Kentucky All Schedule Prescription Electronic Reporting) database was implemented statewide. This electronic database was designed to capture information on prescriptions for controlled substances that are dispensed within Kentucky. The database is quite comprehensive in that it captures information on all schedules of controlled substances for which there is a legitimate medical use--Schedules II-V. Information on out of state dispensing to Kentucky residents (via mail order) is also captured, provided the patient does not visit the dispensing agent in person. This informational system facilitates targeting of individuals (prescribers, dispensers, and end users) who are in violation of Kentucky's Controlled Substances Act. The electronic information system also provides valuable information to prescribing health care professionals on other controlled substances that the patient may be using.

In 2002 duties associated with the Department for Public Health's Drug Control Branch including responsibility for the KASPER reporting system were transferred to the Office of the Inspector General, Cabinet for Health and Family Services. Through this transfer increased emphasis was placed on investigation, follow-up, and enforcement of regulations in situations involving controlled substance abuse. Because of the transfer to an investigational/enforcement unit, there are no plans at this time to pursue some of the preventive measures originally developed by Department for Public Health staff (Objectives 13.3-13.5).

## Progress toward Achieving Each HK 2010 Objective

Summary of Objectives for Medical Product Safety	Baseline	HK 2010 Target	Mid-Decade Status	Progress	Data Source
13.1. Maintain an electronic database of 90% of all prescription controlled substances dispensed to citizens of the Commonwealth.	Database first implemented in FY 2000	≥90%	95% (2005)	Target Achieved	KASPER
13.2. Expand the electronic monitoring system described in Objective 13.1.	a) Lag time in reporting averaged 16 days	Decrease lag time in reporting	Lag-time of reporting not decreasing	No	KASPER
	b) Data not readily available to professionals	Expand availability	Expanded access to health professionals	Yes	
13.3. – 13.5. (DELETED)					